

Message Text

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PAGE 01 COPENH 02866 111657Z

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ACTION HEW-04

INFO OCT-01 EUR-12 ISO-00 SCI-04 DRC-01 RSC-01 /023 W
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R 111533Z OCT 74
FM AMEMBASSY COPENHAGEN
TO SECSTATE WASHDC 9813
INFO AMEMBASSY HELSINKI
AMEMBASSY LONDON
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UNCLAS COPENHAGEN 2866

FOR FDA

E.O. 11652: NA
TAGS: SEL, TBIO, DA
SUBJ: ORAL CONTRACEPTIVES

1. DANISH NATIONAL HEALTH SERVICE, EFFECTIVE OCTOBER 7, 1974, HAS WITHDRAWN APPROVAL FOR PRESCRIPTION AS ORAL CONTRACEPTIVES OF A NUMBER OF MEDICAL PREPARATIONS WITH OVER 50 MICROGRAM ESTRONGEN CONTENT PER PILL. PREPARATIONS MAY STILL BE PRESCRIBED FOR OTHER THAN BIRTH CONTROL MEDICAL PURPOSES.

2. FOLLOWING PREPARATIONS ARE AFFECTED :(CONTENTS ARE INDICATED ACCORDING TO NORDIC PHARMACEUTICAL NOMENCLATURE NFN):

(A) NONOVUL (DANISH AB) WITH CONTENT OF 2.5 MILLIGRAMS LYNESTRENOLUM AND 75 MICROGRAMS MESTRONALUM IN EACH PILL;

(B) OVANON (SWEDISH ERCO) WITH CONTENT OF 7 PILLS, EACH WITH 80MICROGRAMS MESTRANOLUM, PLUS 15 PILLS, EACH WITH 10 MICROGRAMS MESTRANOLUM AND 2.5 MILLIGRAMS LYNESTRENOLUM;

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(C) OVULEN (SERLE) WITH 1.0 MILLIGRAM

ETYNODIOLI ACETAS AND 100 MICROGRAMS MESTRANOLUM
IN EACH PILL;

(D) OVULEN-MITE (SERLE), SAME AS ABOVE
WITH HALF DOSE (0.5 MILLIGRAM) ETYNODIOLI ACETAS;

(E) PLAN (DANISH PHARMACIES LAB) WITH 2.0
MILLIGRAMS NORETHISTERONUM AND 100 MICROGRAM
MESTRANOLUM IN EACH PILL.

3. ACCORDING TO DANISH NHS, WITHDRAWAL OF APPROVAL ON ABOVE PREPARATIONS WAS BASED ON RECOMMENDATION BY NHS MEDICINE CONTROL GROUP. CLINICAL FOLLOW-UP REPORTS INDICATED HIGH FREQUENCY OF CIRCULATORY COMPLICATIONS WITH USE OF HIGH-ESTROGEN PREPARATIONS. NHS INFORMS US THAT THESE AND SIMILAR PREPARATIONS WERE TAKEN OFF APPROVED LISTS IN UK AND SWEDEN EARLIER THIS YEAR AND THAT FINNLAND CONTEMPLATES SIMILAR ACTION. FINDINGS OF MEDICAL CONTROL GROUP RESULTED FROM ROUTINE CLINICAL RESEARCH OVER PROLONGED PERIOD OF TIME. NO DRAMATIC OR FATAL CASES REPORTED. RESEARCH REPORT IS EXPECTED TO APPEAR IN NEXT ISSUE OF DANISH MEDICAL JOURNAL. WILL TRANSMIT WHEN AVAILABLE.
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NNN

Message Attributes

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Disposition Comment:
Disposition Date: 01 JAN 1960
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